

AMENDMENT AND RESPONSE TO SECOND OFFICE ACTION
U.S.S.N. 10/612,463

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Amendment to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. (Currently amended) A kit for intravesicular instillation to a human patient comprising (i) a first container comprising a sterile unit dose of a therapeutic compound selected from the group consisting of resiniferatoxin, tinyatoxin, 20-homovanillyl-mezerein and 20-homovanillyl-12-deoxyphorbol-13-phenylacetate, wherein the therapeutic compound is in the form of a solution concentrate or dry powder and (ii) a second container comprising a sterile physiologically compatible diluent capable of dissolving and maintaining in solution the therapeutic compound, the volume of the diluent being sufficient for intravesicular instillation of the unit dose and providing a concentration of the therapeutic compound of from about 0.05 μM to 2.0 μM upon mixing the diluent with the therapeutic compound that is compatible with bladder mucosa and does not cause meaningful pain or irritation to the patient when administered.
2. (original) The kit of claim 1, wherein the first container contains a solution of resiniferatoxin dissolved in ethanol at a concentration of from 0.5 μM to 20 μM and the second container contains 100 ml of normal saline.
3. (previously presented) The kit of claim 1, wherein the first container contains a lyophilized powder comprising from 0.005 μmole to 0.2 μmole resiniferatoxin and the second container contains 100 ml of 10% (v/v) ethanol in normal saline.
4. (canceled)
5. (previously presented) The kit of claim 1, wherein concentration of the therapeutic compound is between about 0.05 μM and 1.0 μM .

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6. (previously presented) The kit of claim 1, wherein the compound is resiniferatoxin.
7. (previously presented) The kit of claim 1, wherein the second container contains a physiologically compatible solvent comprising an aqueous ethanol mixture having less than about 20% (v/v) ethanol and from about 0-1% (w/v) non-ionic detergent.
8. (previously presented) The kit of claim 7, wherein the solvent further comprises physiologically compatible salts.
9. (previously presented) The kit of claim 8 wherein the solvent comprises physiological saline and a maximum of about 10% (v/v) ethanol.
10. (previously presented) The kit of claim 7, wherein the solvent further comprises buffer salts at a pH within the normal pH range of human urine.
11. (New) A kit for intravesicular instillation to a human patient comprising (i) a first container comprising a unit dose of a therapeutic compound selected from the group consisting of resiniferatoxin, tinyatoxin, 20-homovanillyl-mezerein and 20-homovanillyl-12-deoxyphorbol-13-phenylacetate, present in a sterile storage stable form in stock solution concentrate comprising polyethelene glycol and a first stabilizer wherein the first stabilizer is citric acid, wherein the solution is within the pH range of normal urine, and (ii) a second container comprising a sterile diluent comprising physiological saline and polysorbate 80.
12. (New) The kit of claim 11 wherein the stock solution further comprises a second stabilizer.
13. (New) The kit of claim 12 wherein the second stabilizer is selected from ascorbic acid, cyclodextrin, EDTA, BHT and NF.